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EXAMINER

DAVIS, K

ART UNIT . PAPER NUMBER

1636

9

DATE MAILED:

12/15/00

Please find below and/or attached an Office communication concerning this application or  
pr ceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/458,779

Applicant(s)

LATTERICH ET AL.

Examiner

Katharine F. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 September 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☒ Interview Summary (PTO-413) Paper No(s) 8.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

### **DETAILED ACTION**

This Office Action is in response to the Amendment filed September 18, 2000 and to the telephone interview with Ann Viksnins on September 8, 2000. Claims 1-42 are pending in the instant application.

The objection to the specification (with regard to labeling of the figures) has been withdrawn in view of the amendments to the specification. The rejection of claims 31-34 under 35 U.S.C. § 112, first paragraph has been withdrawn in view of the remarks presented by the applicants on page 6 of the September 18, 2000 Amendment. The rejections of claims under 35 U.S.C. § 112, second paragraph (presented in parts 13-17, 19 and 20 of the Office Action mailed April 10, 2000) have been withdrawn in view of the amendments to the claims and the remarks presented by the applicants on pages 7 and 8 of the September 18, 2000 Amendment.

### ***Claim Rejections - 35 USC § 112***

For the text of those sections of Title 35, U.S. Code not included in this action, see the prior Office Action mailed on April 10, 2000.

Claims 1, 2, 5-13, 16-24, 27-35 and 37-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This rejection is based on the Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement published in the Federal Register (Volume 64, Number 244, Pages 71427-71440). Claims 1, 2, 5-

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13, 16-24, 27-35 and 36-42 are drawn to a polynucleotide comprising a sequence encoding a functional vesicular fusion factor 2 protein (Vff2p) or a structural homolog of Vff2 protein, vectors for expression of said polynucleotide, the Vff2 protein encoded by said polynucleotide, and methods for using said polynucleotide and protein to increase protein production and secretion in a cell. These are genus claims encompassing any protein and/or nucleic acid sequence from any organism having structural homology with the nucleic acid sequence encoding Vff2p and/or the Vff2 protein. The present specification discloses the nucleic acid sequence and the protein (sequence) of Vff2 from the yeast *Saccharomyces cerevisiae*. The disclosure of one reference protein is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision the complete sequence of any other homologous protein and/or nucleic acid based on the disclosed protein and nucleic acid sequence. Additionally, there is no description of a representative number of species by partial structure and a function which correlates with structure as there is no disclosure of the specific protein and/or nucleic acid sequences necessary for activity of Vff2p in the cellular secretory pathway. Therefore, the specification does not describe the claimed protein and nucleic acid sequences in such full, clear, concise and exact terms so as to indicate that the applicants had possession of these sequences (other than SEQ ID NO's: 1 and 2) at the time of filing of the present application. Thus, the written description requirement has not been satisfied.

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Claims 1-42 are rejected under 35 U.S.C. 112, first paragraph because the specification does not reasonably provide enablement for a polynucleotide with a sequence other than that of SEQ ID NO:1, a protein with a sequence other than that of SEQ ID NO:2, or a host cell other than *Saccharomyces cerevisiae*. Applicants argue that the relative skill of those in the art of recombinant engineering and protein expression in yeast is high and also that Vff2 protein is a novel discovery. Applicants requested further clarification of the rejection and asked three questions in the last paragraph on page 5 of the September 18, 2000 Amendment.

“Is the Examiner stating that it is unpredictable for a homolog of Vff2p encoded by a sequence other than SEQ ID NO:1 (or amino acid sequence SEQ ID NO:2) to have the same function as that encoded by SEQ ID NO:1 (or amino acid sequence SEQ ID NO:2)? Or is the Examiner stating that it is unpredictable for there to be homologous Vff2p proteins in species besides *Saccharomyces cerevisiae* ? Or is the Examiner stating that it would be unpredictable how a Vff2p from one species would function if placed in a host cell from a different species? ”

Applicants' arguments presented on pages 4 and 5 of the September 18, 2000 Amendment have been carefully considered but are not found to be convincing. The discovery of the Vff2 protein of *Saccharomyces cerevisiae* by the present inventors does not predict homologous proteins(or homologous nucleic acids encoding such proteins) in other species or if such homologous proteins/nucleic acids are found to exist, function of such homologs cannot be predicted based on homology alone. Additionally, on page 11 of the instant specification applicants admit that the % identity for sequences in other species that may be homologous to Vff2p is low. Therefore, the Examiner believes that the area of the invention in its full scope is unpredictable and would require undue experimentation by one of skill in the art to practice the invention in its full scope by identifying structural homologs of the Vff2 protein and/or structural homologs of nucleic acid sequences encoding the Vff2 protein.

Each of the factors raised by Applicants apply to the unpredictability of the invention. Applicants provide no evidence other homologs exist other than apparent genes with low similarity (see page 11 of the specification). Additionally, Applicants provide no evidence that potential homologs have the same function. Therefore, for the reasons stated above and in the previous Office Action mailed April 10, 2000, the rejection of claims 1-42 under 35 U.S.C. 112, first paragraph is maintained.

Claims 37-42 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in that they do not recite a positive process step that clearly relates back to the preamble.

Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-42 are indefinite for the recitation of the phrase "structural homolog(s)". The definition of structural homolog in the instant specification on page 4, line 21 does not adequately define the metes and bounds of the claims.

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***Conclusion***

Claims 1-42 are rejected. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Schwartz can be reached on (703) 308-1133. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry concerning the formalities of this application should be directed to Patent Analyst Dianiece Jacobs whose telephone number is (703) 305-3388. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Katharine F. Davis/KFD  
December 14, 2000

  
ROBERT A. SCHWARTZMAN  
PRIMARY EXAMINER